“Prosthetics 2020 (or 2016?)”

AOPA Leadership Conference
Palm Beach, FL
January 10th, 2015

Doug Smith, MD
University of Washington

Kenton Kaufman, PhD
Mayo Clinic

Sam Liang
Hanger Clinic
Innovation improves outcomes and can lower costs of care to the Health Care System

1. Great for Patients!
2. We get Paid!
The recent LCD proposal is a clear signal that the health economic value of the O&P profession needs to be established.
Prosthetic 2020 Purpose

“To protect and grow the Lower Extremity Prosthetic (“LEP”) market through an outcomes based medicine approach that timely prosthetic services saves lives and money”

This will be accomplished by:

1. Defining and establishing the health economic value of current LEP products/services (K3/K4)

2. Expanding the value of LEP products/services by defining new patient indications and population that will benefit from current and new prosthetic technologies (K1/K2)
Prosthetic 2020 Goals

1. Improve the future reimbursement landscape for LEP

2. Define and provide the appropriate technology to the appropriate patients to reduce the current trend of providing the lowest cost technology to all patients

3. Define new patient segments that can benefit from LEP technology

4. Separate the O&P profession from Durable Medical Equipment (DME) in the mind of the payers
Medicare RAC, Pre-Pay and Cert Audits have increased significantly in the last 2 years. 50% to 75% of them focused on Lower Extremity Prosthetics: MPK and associated components. High dollar items and lack of evidence make these an easy target for Payers.

Market Outlook:
- Prosthetics: +
- Orthotics: -
- Shoes/Inserts: -

1. Start: Lower Extremity Prosthetics: Single Largest Category of Revenue/Profit
2. Future analyze / identify next target: High value custom Orthoses

RATIONALE: THE LOWER EXTREMITY MARKET AT $1.7 B IS O&P’S SINGLE LARGEST MARKET

2016 (E) Market Size
- Prosthetics: $1.7 B
- Orthotics: $1.9 B
- Shoes: $0.8 B
- Inserts: $0.8 B

~$4.4 billion

Market Size

1.7
1.9
0.8

Prosthetics
Orthotics
Shoes
Inserts

2016 (E)
Criteria for Change or Modification of Reimbursement

1. Identify Important Clinical Need
2. Compelling Clinical Data
3. Demonstrate Value & Inadequacy of Payment
4. Stakeholder Support

The good news is that the O&P profession has made progress on multiple fronts in Lower Extremity Prosthetics.
Rapid Progress: Moving Prosthetics 2020 Forward

Charter, Identify and Recruit Medical Advisory Board

Jan - June’15

5-8 core members
- Vascular/Orthopedic MD’s
- Physiatrists
- Biomechanics Expert
- HECON/Reimbursement
- Consultants as needed

June - Oct’15

Determine/Propose ‘meaningful’ ‘Clinical and Health Economic metrics for Payers

- Specific LE measures: TUG, Gait, Falls, Stability, etc.
- HECON: QOL
- Global: Blood Pressure, H1AC, Medications, etc.

July’15 - Mar ‘16

Conduct Systematic, literature and data reviews with potential Meta Analyses

- Dobson / DaVanzo
- Align AAOP and all other R&D efforts
- Other data sources

Mar’16 - TBD

If data doesn’t exist, then generate data via well designed Clinical Studies

2017+

Positive Policy and Coverage Decisions

* Achieving/Demonstrating Coverage, Coding, Payment, and Medical Necessity

Develop and engage CMS (DC and 4 DMEMAC’s) and execute Advocacy programs (MOBILTY SAVES) along with Publication and Podium plan with frequency timed to Federal Coverage Cycles

* Achieving/Demonstrating Coverage, Coding, Payment, and Medical Necessity
Process: Life Cycle Management to **grow** the market

Positive Policy and Coverage Decisions

- Registry – Market Surveillance Studies
- Additional HECON analyses
- New patient segments
- New Studies
- Next O&P area
- Advocacy
- Communications: Publication and Podium

Value Expansion
- Longitudinal Data for Existing Patients
- Commercial Payers
- New Patient subsets
- New Technologies

Projects
- FAST K2 Study – K2-K3 LEP technology
- Planned AOPA Registry

Market

$1.7 B

$3+ B
SPECIFIC PATHS TO SUCCESS BY PROVIDING AN OUTCOMES BASED MEDICINE VALUE PROPOSITION – MUST MAKE IT ‘EASY’ FOR CMS

1. Immediate to short term: Propose and rationalize new L-Codes, Revise/redefine current L-Code language

2. Medium term: Propose new methodology for the underlying payment calculations for certain L-Codes

3. Long term: Provide a new methodology for payments such as “Patient Case Rate” fee – shift to risk sharing arrangements
Prosthetics 2020

An AOPA administered program funded by members:

A Steering Committee has been established with members from each sponsoring company and AOPA
Prosthetics 2020

“A Surgeon’s and MAB’s Member’s Perspective”
3 Working Groups

1. Selection of Endpoints / Measures that Payers “care about”

2. Translation into HECON value that Payers understand

3. Continued Data Mining of CMS Prosthetic data (Dobson DaVanso analyses 2.0)
Working Group’s Leadership

1. Selection of Endpoints / Measures that Payers “care about”

2. Translation into HECON value that Payers understand

3. Continued Data Mining of CMS Prosthetic data (Dobson DaVanso analyses 2.0)

- Dr. K. Kaufman, Mayo Clinic
- Dr. A. Kannenburg, Ottobock
- K. DeRoy, Ossur
- Dr. S. Zaheedi, Endolite
- Dr. R. Gailey, University of Miami
- P. Stevens, Hanger Clinic

- Dr. J. Campbell, AOPA, Hanger
- S. Liang, Hanger
- J. Martin, Freedom

- T. Fise, AOPA
- C. Dankmeyer, AOPA
- A. Dobson, Dobson-DaVanso
- A. El-Gamil, Dobson-Davanso
Workgroup Interdependencies and Deliverables

**Workgroup 1**

**Measures**

- **Short Term**
  - Balance
- **Medium Term**
  - Walking Capabilities
    - Timed walk test
    - TUG
    - Speed
    - Other, etc.
  - Patient Satisfaction
    - Pain
- **Long Term**
  - Global
    - Blood Pressure
    - H1AC
    - Arthritis
    - Survival

**Endpoints**

- **‘Payers Care About’**
  - Balance
  - Fall reduction
  - Hospitalization reduction
  - Out Pt vs. In Pt. ratio increase
  - Walking Capabilities
    - ADL increase
    - QOL improvement
    - Weight loss (BMI)
  - Patient Satisfaction
    - Medication reduction
  - Global
    - Morbidity benefit
    - Mortality benefit
    - Diabetes improvement

**Workgroup 2**

- HECON Calculations
- $ Value Proposition
- CMS Proposals
- L-Code revisions
- Methodology calculations
- Demonstration projects (‘DP’)

**Prosthetics 2020 Plan**

- **2016**
  - Dob-Davanso (WG3)
  - K3/K4 focus
- **2017**
  - L-Code Revisions
- **2018**
  - AOPA Registry results
  - Methodology re-calculation
  - K1/K2 DP

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“Illustrative”
Keys to 2020 Implementation

“Win-Win” Analyses and Proposals as CMS would do it...

Outcomes “Payers care about”

Research

Evidence
Working Group Updates

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National Prosthetic Registry
Initial Steps

Kenton Kaufman, PhD, PE
W. Hall Wendel Jr. Musculoskeletal Research Professor
Professor of Biomedical Engineering
Director, Motion Analysis Laboratory
Consultant, Departments of Orthopedic Surgery, Physiology, & Biomedical Engineering

Prosthetics 2020
& The Registry Project
National Prosthetics Registry

Limb Loss
- Hospital
  - Open to variety of data types and sources
  - Automatic to the greatest extent possible
  - Tied with existing systems and processes
  - Integrated systems and functionality with key national EMRs
- Patient

Data Architecture
- Server
  - Open & agile
  - Ease of use
  - Reporting flexibility

Analytics
- Integrated clinical user groups
- Attention to workflow
- Design features enable success
- Critical components grow in complexity through phases of development

Outcomes
- Custom & standard reporting
- Support operations goals as well as detailed research objectives
- Support and architected systems for specific civilian and veteran clinical needs

Data Collection

Data Quality

Usability

Reporting

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Partner
American Joint Replacement Registry

• Independent, multi-stakeholder, not-for-profit 501(c)(3) organization

• Goal: Optimize patient outcomes

• Mission:
  • Improve quality of care
  • Reduce cost of care
  • Enhance patient safety

• Board of Directors

• Public Advisory Board

• 612 hospitals, 4,441 surgeons

Data on 354,000 procedures since 2008!
Data Collection

Data Elements

• Tiered system

• Level I – *Amputation/Hospitalization Documentation*

• Level II – *Prosthetic Fitting*

• Level III – *Patient Reported Outcome Measures*

• Level IV – *Objective Functional Outcomes*
Data Elements

Level I – *Amputation/Hospitalization Documentation*

- Age
- Gender
- Ethnicity
- Veteran
- Insurance
- Occupation
- Amputation Characteristics
- Discharge
- Therapy
- Physical Exam
- Functional Capability
- Status of Wound Healing
Data Elements
Level II – Prosthetic Fitting

• Physical Exam by Ordering MD
• Expected functional potential (K-Level)
• Walking Aids
• Components

• Lower Extremity Function
  • Locomotor Capability Index (LCI)
  • Prosthetic Limb Users Survey of Mobility (PLUS-M)
  • Patient Specific Functional Scale (PSFS)

• Activity Monitoring
Data Elements
Level III – *Patient Reported Outcome Measures*

- Socket Comfort Score
- Patient Satisfaction
- Safety
  Activity Specific Balance Confidence (ABC) Scale
- Co-Morbidities
  - Pain
  - Western Ontario and McMaster Universities Arthritis Index (WOMAC)
  - Oswestry Disability Index
Data Elements
Level IV – *Objective Functional Outcomes*

- Mobility and Balance
  - Timed Up-and-Go (TUG) – for K1 & K2 amputees
  - Four Square Step Test (FSST) – for K3 & K4 amputees
- Gait Society/Lower Limb Prosthetic Society Forum: L test
- 6 minute walk test + Rating of Perceived Exertion (RPE)
- Amputee Mobility Predictor (AMP)
- Amputee Mobility Predictor – No prosthesis (AMPnoPRO)
## Registry Executive Committee

<table>
<thead>
<tr>
<th>Name</th>
<th>Affiliation and Position</th>
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<tbody>
<tr>
<td>Kenton Kaufman, PhD, PE</td>
<td>Mayo Clinic: W Hall Wendel Jr. Musculoskeletal Research Professor</td>
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<tr>
<td>Tom Fise, JD</td>
<td>American Orthotic and Prosthetic Association: Executive Director</td>
</tr>
<tr>
<td>James Campbell, PhD, CO</td>
<td>American Orthotic and Prosthetic Association: President</td>
</tr>
<tr>
<td>Jeffrey P. Knezovich, CAE</td>
<td>American Joint Replacement Registry: Executive Director</td>
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<tr>
<td>Bill Oldham, MBA</td>
<td>Cogenz International: President</td>
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<tr>
<td>Fred A. Cecere, MD</td>
<td>Thought Leadership and Innovation Foundation: Executive Director</td>
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<tr>
<td>Kurtis Hoppe, MD</td>
<td>American Academy of Physical Medicine and Rehabilitation: Past-President</td>
</tr>
<tr>
<td>LTC Owen T. Hill, PhD</td>
<td>Department of Defense: Chief- Research &amp; Surveillance Division - Extremity Trauma and Amputation Center of Excellence (EACE)</td>
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<tr>
<td>CPT M. Jason Highsmith, PT, DPT, PhD, CP, FAAOP</td>
<td>Veterans Administration: Deputy Chief- Research &amp; Surveillance Division - EACE</td>
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<tr>
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<tr>
<td>Registry Science</td>
<td>Bill Oldham, MBA</td>
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<tr>
<td>Outcomes Assessment</td>
<td>Jason M. Wilken, PT, PhD</td>
</tr>
<tr>
<td>Information Security &amp; Data Quality</td>
<td>Sheri LaBonte, JD, CISSP, PMP, CSM</td>
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<tr>
<td>Analytics</td>
<td>Roger Chaufournier, MHSA</td>
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<tr>
<td>Legal/patient privacy</td>
<td>Peter Thomas, JD</td>
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<tr>
<td>Health Policy</td>
<td>Kurtis Hoppe, MD</td>
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<tr>
<td>Health IT</td>
<td>Randy Regimbal, CISSP</td>
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<td>Ex-Officio</td>
<td>Tom Fise, JD</td>
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### Stakeholder Advisory Board

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<td>Tom Fise, JD</td>
<td>AOPA: Executive Director</td>
</tr>
<tr>
<td>Public Health</td>
<td>Stephen T. Wegener, PhD</td>
<td>Johns Hopkins: Professor of Health Policy and Management at the Bloomberg School of Public Health</td>
</tr>
<tr>
<td>Product Manufacturer</td>
<td>James Colvin, MS</td>
<td>Ohio Willow Wood: Director-Research and Technology</td>
</tr>
<tr>
<td>Prosthetic Service Provider</td>
<td>Paul E. Prusakowski, CPO, FAAOP</td>
<td>OPIE Electronic Medical Record: CEO</td>
</tr>
<tr>
<td>Payer</td>
<td>Tom Phelan, CPA</td>
<td>Chesapeake Employers Insurance: President &amp; CEO</td>
</tr>
<tr>
<td>Patient</td>
<td>CPT (ret) Matthew D. Bacik, MBA</td>
<td>Bacik Group: CEO</td>
</tr>
<tr>
<td>Academic Institution</td>
<td>Wendy Beattie, CPO, FAAOP</td>
<td>Eastern Michigan University: Clinical and Program Director</td>
</tr>
<tr>
<td>Professional Society</td>
<td>Lydia Middleton, MBA, CAE</td>
<td>American Academy of Orthotists and Prosthetists: Executive Director</td>
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Prosthetics 2020

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Working Group Updates

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Working Group 2 Update

1. Screening world class Health Economic – Reimbursement (HECON-R) consulting firms with selection in Q1
   - Rand
   - Avalere
   - Covance
   - Quorum

2. Development of overall CMS strategy and initial HECON-R analyses in Q2-Q3’16

3. Execute strategy and plan in Q4’16
Working Group Updates

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Ongoing Dobson-DaVanzo Work
Mining the Medicare Database

- Publication of Dobson-DaVanzo base study in a peer reviewed journal
- Data and custom cohorts being secured for 2011-2014 to allow study replication
  - Trend of lower limb prosthesis reimbursement may operate to increase value proposition
Ongoing Dobson-DaVanzo Work
Mining the Medicare Database

• 2011-2014 data will include Part D drug expenses to be extrapolated back for inclusion in 2007-2010 data
• Large compendium of all Dobson-DaVanzo data and analysis available to AOPA members (log-in required)
Ongoing Dobson-DaVanzo Work

Mining the Medicare Database

- Deeper dive into orthotic data
- Review of K2/K3 functional level data to determine whether K-level eligibility for advanced prosthetics may be “upside-down”
Next Steps

1. Execute Working Group deliverables

2. Continue CMS and DMEMAC outreach

This is our Profession
Please join Prosthetics 2020!
Close: Prosthetics 2020

“A Surgeon’s and MAB’s Member’s Perspective”
THANK YOU!
National Prosthesis Registry Cloud (NPRC)

Web/Wireless/Mobile Apps - User Environments/Interfaces

PRIVATE HYBRID CLOUD Infrastructure

Legacy (AJRR)+/Applications/Services

Knowledge Portal (Open Source)

User Interface

Internal/External

Secure Single Sign On

Advanced Discovery Services

Data Analysis

Dynamic Reasoning Engines

Content Management

Org/Teams

Individuals

Research Analysis Tools

Document Management

News

Blogs

Wiki

Social Nets

DBase Environments

Intelligent Technologies

Directory

Research Tool

Enterprise Mgt. Services

Service Desk

Monitoring and reporting

System Management

Data Mgt. Services

Net Services

Cloud Mgt. Services

Data

Patient Safety & QA

Improve P-Tech

Best Practices

Guide Research

Influence Policy

NPR Outcome Goals

Cyber Security - Information Assurance/Insider Threat/Continuous Monitoring

FedRAMP/HIPAA/FISMA/DIACAP
Business Model

• Subscription or membership fee
  • Fee per user or site
  • Reporting via web portal

• Data services or research model
  • Standard – automated and delivered in a variety of settings
  • Custom – heterogeneous, labor intensive
  • Research driven
    • Partnerships with federal, corporate, non-profits, individuals
    • Grant work – subject recruitment
    • Data sharing
  • Data services
    • Industrial partners – product robustness, market penetration

• Hybrid
The Common Rule

- Covers research involving human subjects
- **HHS Office for Human Research Protections** has stated that data collected in the course of clinical care that is submitted to external researchers is not human subjects research and therefore is not subject to the Common Rule
- **HIPAA Compliance** is mandatory
Summary

- Health care is moving from pay-for-service to pay-for-quality
- National O&P Registry is needed
  - Reflects clinical practice
  - Evaluate resource utilization for common interventions across diverse geographic regions or practice settings
  - Identify adjustable provider- or hospital-level variables associated with complications or quality outcomes
  - Identify premature component failures
  - Quantify patient outcomes
Questions & Discussion